



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/814,705

03/30/2004

J. Richard Gyory

ALZA-0377/ALZ5016USANP

7214

45511 7590 03/18/2008

WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

03/18/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@woodcock.com

Office Action Summary	Application No. 10/814,705	Applicant(s) GYORY, J. RICHARD	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/31/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/31/2008 has been entered.

Acknowledgments

2. This office action is in response to the reply filed on 1/31/2008.
3. In the reply, the applicant cancelled claims amended claim 17.
4. Thus, claims 17-21 are pending for examination.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 17 recites the limitation "the reservoir" in ln 2. There is insufficient antecedent basis for this limitation in the claim.
7. Claim 17 recites the limitation "the reservoir housing" in ln 4-5, 8. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3767

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 17-21 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Flower (5857994). Flower discloses an electrotransport device (Fig 1) comprising: a non-conductive reservoir housing (4) for the reservoir of the electrotransport device comprising a substantially flexible electrically conductive element (8, 26) integrally molded within the non-conductive housing (Fig 1-2, wherein the housing 4 is shown by the dotted lines in Fig 2 and the conductive element is shown outside the housing 26 and entering the housing 4 to contact 8), wherein a first portion (portion of 26 that contacts 8 inside the housing 4 – whose boundaries are shown by dotted lines in Fig 2) of the conductive element is within the reservoir housing and a second portion (portion of 26 outside of the dotted lines of 4 and that goes and contacts 27 – Fig 1, 2) of the element is disposed on the outside of the reservoir housing and extends therefrom, and wherein a substantially liquid and moisture-impermeable bond is created between the material forming the reservoir housing and the conductive element (Fig 1-2; col 4, lns 18-24, 36-44; discussion below in Response to Arguments); wherein the reservoir housing is a single integral component (4, Fig 1, 2); wherein the electrotransport device is manufactured without the fabrication of openings or other passages through the reservoir housing (4, Fig 1, 2); wherein the

conductive element comprises a substantially planar member (26, Fig 1); wherein the conductive element includes a base member having a conductive coating disposed thereon (26; Fig 1, col 4, lns 28-31).

10. Flowers does not explicitly disclose that the conductive elements (8, 26) and the reservoir housing (4) form a substantially liquid and moisture-impermeable bond.

However, it would be obvious to one of ordinary skill in the art at the time the invention was made to the seal between the conductive elements (8,26) and (4) inherently has substantially liquid and moisture-impermeable characteristics (see MPEP 2112). It is clear that the housing is substantially liquid and moisture impermeable because the housing contains liquid therapeutic agents, saline, or conductive gels (col 4, lns 18-24, 36-44). Additionally, it is clear that the electrical connectors (8, 26) are housed both inside the housing (8, 26) and external to the housing (26; discussion above). As shown in Figs 1-2, the electrical connectors (8 and 26) are clearly sealed into housing 4 and as electrical connectors (26) travel to tab (32) and connect with exposed connector (34). Since the electrical connectors (8, 26) contact the reservoirs and the liquid therapeutic agents, saline, or conductive gels housed therein and additional travel outside the housing to tab (32) and exposed connector (34) and this occurs via a seal between the housing and the electrical connectors and result in no leaking or loss of reservoir fluid, it is obvious and necessarily flows from Flowers that the seal/bond created between the material forming the reservoir housing and the conductive element is substantially liquid and moisture-impermeable.

11. Claims 17-21 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kuribayashi et al (6915159). Kuribayashi et al discloses an electrotransport device (Fig 1-12) comprising: a non-conductive reservoir housing for the reservoir of the electrotransport device comprising a substantially flexible electrically conductive element (2, 14, 15, Fig 1a-c, 5a-b, 6a-c) integrally molded within the non-conductive housing (1), wherein a first portion (2, 14, or 15, that contacts conductive drug layer 9, 12, or 13 – Fig 1a-c, 5a-b, 6a-c) of the conductive element is within the reservoir housing and a second portion (2, 14, 15 that is exterior and forms exterior connector that can be connected to 18 – see Fig 5b, 6b-c, 8) of the element is disposed on the outside of the reservoir housing and extends therefrom, and wherein a substantially liquid and moisture-impermeable bond is created between the material forming the reservoir housing and the conductive element (Fig 1a-c, 5a-b, 6a-c, 8; col 3, Ins 20-25, 53-55, 60-col 4, Ins 5, Ins 12-14, 44-46; col 5, Ins 59-64, col 6, Ins 6-9, Ins 28-39; col 7, Ins 63-65; col 8, Ins 13-16; col 19, Ins 20-57; and col 21, Ins 42-45; and discussion below); wherein the reservoir housing is a single integral component (1; Figs 1, 5a-d, 6a-c, 8); wherein the electrotransport device is manufactured without the fabrication of openings or other passages through the reservoir housing (Figs 1, 5a-d, 6a-c, 8); wherein the conductive element comprises a substantially planar member (2, 14, 15; Figs 1, 5a-d, 6a-c, 8); wherein the conductive element includes a base member having a conductive coating disposed thereon (col 7, Ins 1-5, 39-47).

12. Kuribayashi et al does not explicitly disclose that the conductive elements (8, 26) and the reservoir housing (4) form a substantially liquid and moisture-impermeable bond. However, it would be obvious to one of ordinary skill in the art at the time the invention was made to the seal between the conductive elements (8,26) and (4) inherently has substantially liquid and moisture-impermeable characteristics (see MPEP 2112). First, the teachings of Kuribayashi et al (Fig 1a-c, 5a-b, 6a-c, 8; col 3, lns 20-25, 53-55, 60-col 4, lns 5, lns 12-14, 44-46; col 5, lns 59-64, col 6, lns 6-9, lns 28-39; col 7, lns 63-65; col 8, lns 13-16; col 19, lns 20-57; and col 21, lns 42-45) clearly disclose a desire and capability for substantially liquid and moisture-impermeable seals between components to maintain proper drug stability and sealing of the conductive layers. Explicitly disclosed is the fact that the materials used in constructing the reservoir housing are water-impermeable materials, water-proof, and oil proof. Additionally, explicitly disclosed is the fact that a water evaporation test that tested the devices ability to maintain liquid within the reservoir housing without evaporation loss resulted in nearly 100% retention. Finally, the conductive elements (2, 14, 15) are within the housing (1) in direct contact with the liquid reservoirs and are external to the housing (ie shown in 14, 15, Fig 6b) and are connected to external power via connector (18; Fig 8; additionally see above citations for discussion in specification). Since the electrical connectors (2, 14, 15) contact the reservoirs and the liquid reservoirs and additional travel outside the liquid impermeable housing (1) to be connected to power source (18) and this occurs via a seal between the housing and the electrical connectors and results in no leaking or loss of reservoir fluid (see above citations), it is obvious and necessarily

flows from Kuribayashi et al that the seal/bond created between the material forming the reservoir housing and the conductive element is substantially liquid and moisture-impermeable.

Response to Arguments

13. Applicant's arguments filed 1/31/2008 have been fully considered but they are not persuasive.

14. The Applicant argues that Flower and Kuribayashi et al do not teach or disclose a substantial liquid and moisture-impermeable bond created between the material forming the reservoir housing and the conductive element. The Applicant argues that the Office has failed to establish the asserted inherency that the bond is necessarily present and necessarily flows from the teachings of the applied prior art.

15. The Examiner respectfully disagrees. See above discussion of claim elements in 35 USC 102/103 rejections – specifically paragraph 10 and 12.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767